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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/640,853	08/13/2003	Randall V. Sparer	P-10998.00	9178

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MUETING, RAASCH & GEBHARDT, P.A.
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EXAMINER

ROGERS, JAMES WILLIAM

ART UNIT	PAPER NUMBER
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1618

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/11/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No. 10/640,853	Applicant(s) SPARER ET AL.	
	Examiner James W. Rogers, Ph.D.	Art Unit 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 March 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1-18 and 20-78 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-18 and 20-78 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Amendment entered

The amendments to the claims filed 03/06/2007 have been entered.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-18 and 20-78 are rejected under 35 U.S.C. 102(b) as being unpatentable by Hossainy et al. (US 6,153,252), for the reasons set forth in the previous office action dated 12/06/2006.

Applicants arguments/remarks filed 03/06/2007 have been fully considered but are not persuasive.

Applicants asserts that Hossainy fails explicitly or inherently teach each and every element of the amended claims which recite a method that includes some variation of selecting a second polymer to be miscible with a first polymer provided elsewhere in the claim in order to form a miscible blend particularly suited for tunable delivery of an active agent.

The relevance of this assertion is unclear. Clearly Hossainy teaches a method of forming a coating for a stent, the coating can be comprised of the same polymer blend as applicants claimed invention, since the polymers are the same it is inherent they will

have the same solubility parameters and the difference between the solubility parameters of the polymers will also be the same. It appears as though applicants are claiming an unknown property (the difference between the two polymers solubility parameters) of an old combination. Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of either anticipation or obviousness has been established. Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. In re Best, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977).

Claims 1-18 and 20-78 are rejected under 35 U.S.C. 102(b) as being unpatentable by Whitbourne et al. (US 6,110,483), for the reasons set forth in the previous office action dated 12/06/2006.

Applicants asserts that Whitbourne fails explicitly or inherently teach each and every element of the amended claims which recite a method that includes some variation of selecting a second polymer to be miscible with a first polymer provided elsewhere in the claim in order to form a miscible blend particularly suited for tunable delivery of an active agent.

The relevance of this assertion is unclear. Clearly Whitbourne teaches a method of forming a coating for biomedical devices, the coating can be comprised of the same polymer blend as applicants claimed invention, since the polymers are the same it is inherent they will have the same solubility parameters and the difference between the

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solubility parameters of the polymers will also be the same. It appears as though applicants are claiming an unknown property (the difference between the two polymers solubility parameters) of an old combination. Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of either anticipation or obviousness has been established. Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. *In re Best*, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-18 and 20-78 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hossainy et al. (US 6,153,252), for the reasons set forth in the previous office action dated 12/06/2006.

Applicants arguments/remarks filed 03/06/2007 have been fully considered but are not persuasive.

Applicants asserts that Hossainy fails to set forth each and every element of the amended claims which recite a method that includes some variation of selecting a second polymer to be miscible with a first polymer provided elsewhere in the claim in order to form a miscible blend particularly suited for tunable delivery of an active agent.

The relevance of this assertion is unclear. Clearly Hossainy discloses a method of forming a coating for a stent, the coating can be comprised of the same polymer blend as applicants claimed invention, since the polymers are the same it is obvious they will have the same solubility parameters and the difference between the solubility parameters of the polymers will also be the same. It appears as though applicants are claiming an unknown property (the difference between the two polymers solubility parameters) of an old combination. Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of either anticipation or obviousness has been established, Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make

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the claim patentable. In re Best, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977). Furthermore, as noted in the previous office action the Perez reference showed evidence that it was already understood in the art to use solubility parameters to predict if polymers would be miscible with each other. Thus it was already known in the art to select polymers that would be miscible with one another based upon their solubility parameters.

Claims 1-18 and 20-78 are rejected under 35 U.S.C. 103(a) as being unpatentable over Whitbourne et al. (US 6,110,483), for the reasons set forth in the previous office action dated 12/06/2006.

Applicants asserts that Whitbourne fails to set forth each and every element of the amended claims which recite a method that includes some variation of selecting a second polymer to be miscible with a first polymer provided elsewhere in the claim in order to form a miscible blend particularly suited for tunable delivery of an active agent.

The relevance of this assertion is unclear. Clearly Whitbourne discloses a method of forming a coating for a biomedical devices, the coating can be comprised of the same polymer blend as applicants claimed invention, since the polymers are the same it is obvious they will have the same solubility parameters and the difference between the solubility parameters of the polymers will also be the same. It appears as though applicants are claiming an unknown property (the difference between the two polymers solubility parameters) of an old combination. Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case or either

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anticipation or obviousness has been established, Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. In re Best, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977). Furthermore, as noted in the previous office action the Perez reference showed evidence that it was already understood in the art to use solubility parameters to predict if polymers would be miscible with each other. Thus it was already known in the art to select polymers that would be miscible with one another based upon their solubility parameters.

Double Patenting

Applicants asserted in their arguments/remarks filed 03/06/2007 that upon indication of otherwise allowable subject matter and in the event the rejection is maintained applicants will provide an appropriate response.

Since applicants have not addressed the double patenting rejection in the previous office action and the claims as amended do not contain allowable subject matter the rejection for double patenting of claims 1,3-9,20,22-27,29-32,34-61,63-69,71,73 and 74-78 over claims 1-57 of copending Application No. 10/640,714 set forth in the previous office action dated 12/06/2006 still stands.

Conclusion

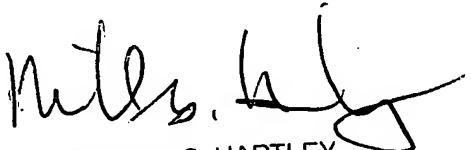
No claims are allowed at this time.

Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James W. Rogers, Ph.D. whose telephone number is (571) 272-7838. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Hartley can be reached on (571) 271-0616. The fax phone number for the organization where this application or proceeding is assigned is 572-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


MICHAEL G. HARTLEY
SUPERVISORY PATENT EXAMINER